Quarterly Progress Report #1

N01-NS-5-2365

Restoration of Hand and Arm Function by Functional Neuromuscular Stimulation

Period covered: September 30, 2005 to December 31, 2005

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A. Executive Summary

1. Contract goals

The overall goal of this contract is to develop and deploy a family of neuroprostheses that can restore arm and hand function to almost any individual with significant paralysis due to cervical spinal cord injury. This contract includes three primary components that are aimed at making this possible:

a. <u>Technology development</u>

i. Development of an implantable 4-channel EMG module by an industrial partner
ii. Purchase of an implantable 8-channel stimulation module from an industrial partner
iii. Development of a fully implanted bipolar EMG electrode

b. <u>Neuroprosthesis deployment</u>

i. 8-channel stimulation, switch-controlled neuroprosthesis for C6 SCI (4 participants)
ii. 16-channel stimulation, 8-channel EMG controlled neuroprosthesis for C5-C6 SCI (4 participants)
iii. 16-channel stimulation, 8-channel EMG controlled neuroprosthesis for C1-C4 SCI (1 participant)

c. <u>Development of high performance command and control interfaces</u>

i. EMG-based control approaches
ii. Integration of brain-machine interfaces into neuroprosthesis control

2. Overview of this reporting period

This is the initial quarterly progress report for this contact. During this three-month period, we have begun putting in place the tools and components that will be needed to deploy several neuroprosthesis systems later in the project. These neuroprosthesis systems will include new, commercially manufactured components and innovative command and control approaches. As detailed in the following section, we have almost completed the negotiation of a subcontract with NDI Medical, inc. to develop a four-channel implantable EMG module, obtained local IRB approval for a general user “screening” protocol, made significant progress on the development of a real-time musculoskeletal model, and assembled the software components needed to visualize the resulting arm movements.

B. Activity Summary

- Subcontract negotiated (in principal) with NDI Medical to develop a four-channel implantable EMG module.
- Obtained approval from the MetroHealth Medical Center Institutional Review Board for a general screening protocol for identifying appropriate participants for the neuroprostheses to be deployed under this contract.
- A software framework for developing a real-time musculoskeletal model of the human arm and hand has been determined. An incremental approach for developing models of gradually increasing realism (and complexity) has been devised. An initial two-

dimensional, 6-muscle model of the arm was assembled and demonstrated to execute at a speed 50 times greater than real-time.

- Software for generating realistic visual renditions of the human arm has been identified, and a basic articulated arm that can be manipulated in real-time for command source training and evaluation has been assembled in a virtual reality environment.
- Generated interest in getting other laboratories to utilize our arm/hand simulator and visualization system for command and control development for upper limb movements. This was done by advertising its future availability during a Brain-Machine Interface poster session at the Society for Neuroscience conference (Nov 2005). We had 32 people sign up to be on the mailing list for more information as it becomes available.

C. Research Results and Discussion

1. Development of implantable 4-channel EMG module

Rationale: All of the neuroprosthesis systems to be deployed during this contract will utilize the Micropulse family of implanted stimulators, and many of these will use a user command and control interface based on EMG recordings from muscles with retained voluntary function. We are subcontracting with NDI Medical to develop a 4-channel implantable Micropulse EMG module (Figure 1) that is easily integrated into a neuroprosthesis system that also includes one or more stimulation modules.

Results: Members of the Case team have met several times with NDI Medical to develop a schedule for the design and fabrication of the Micropulse EMG module. This schedule is summarized below and will be included in the official subcontract that will be submitted to NINDS for approval.

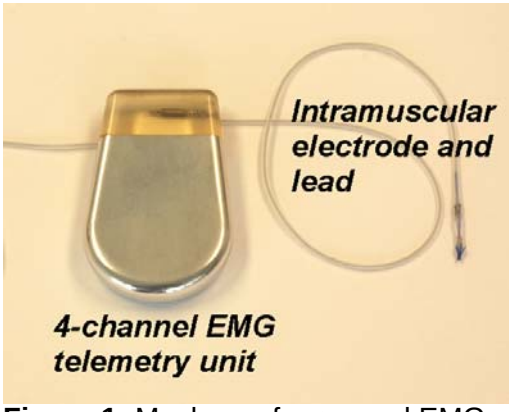

Figure 1: Mock-up of proposed EMG telemetry unit with one of four EMG electrodes shown.

Year 1 (September 2005 – August 2006)

- Design and tooling of Implantable Pulse Generator (IPG) package, including IPG header
- Specify battery and complete associated power management circuitry
- Complete the electronic design and layout of the 8-Channel IPG flexible circuit board
- Measure and test wireless communications hardware for the MES Processor
- Simulate and prototype MES acquisition summary and firmware
- Finalize wireless communication protocol s for 8-Channel IPG & MES Processor
- Specify interface methods for External Controller

Year 2 (September 2006 – August 2007)

- Complete fabrication procedures and qualification testing of the 8-Channel IPG
- Complete design and layout of the MES Processor flexible circuit board
- Finalize MES Processor firmware (operations, communications, and preliminary signal processing)
- Complete External Controller interface and associated firmware/software

- Complete fabrication procedures and qualification testing of the MES Processor
- Finalize packaging and sterilization
- Provide required technical documentation to support IDE submission to FDA

Discussion and interpretation: When this two-year subcontract is completed, NDI Medical will be ready to deliver fully-functional four-channel implantable EMG modules for use in the neuroprosthesis systems deployed to be deployed under this contract.

Future plans: The schedule for the entire two-year subcontract is summarized above.

2. Human subjects (IRB) protocol for participant screening

Rationale: A number of neuroprosthesis systems will be deployed under this contract to individuals with a range of spinal cord injury levels. Many of our potential participants come via referral from physicians without direct knowledge of our goals or of the particular group targeted by our interventions, and from self-referral by individuals with SCI who may not be able to describe their condition sufficiently clearly to determine if they are even close to the inclusion criteria of the study. We have thus developed a “general screening” protocol to perform an initial evaluation of all potential participants and to determine if they qualify for our study. This screening protocol consists of a set of very simple, low risk evaluations intended to determine (1) the functional status of an individual with cervical spinal cord injury and (2) the suitability of this individual for the interventions described in our contract proposal.

Results: The screening protocol was submitted to the MetroHealth IRB on 10/17/2005, underwent scientific review by the local GCRC (General Clinical Research Center) on 11/21/2005, was reviewed by the full IRB on 12/13/2005, and was finally approved (after some minor clarifications) on 12/28/2005. The protocol and supporting documents were submitted to NINDS for review on 1/4/2006.

Discussion and interpretation: Once approved by NINDS, this protocol will allow us to begin evaluating potential participants for the planned neuroprosthesis deployment.

Future plans: Await NINDS approval, then begin screening potential participants.

3. Development of a Real-Time Dynamic Arm Simulator (DAS)

Rationale: The development of the real-time model, or Dynamic Arm Simulator (DAS), has been broken down into three phases to allow each aspect to be fully tested without adding complexity any earlier than necessary. The three versions of the model are as follows:

- DAS1: The first version of the model is a 2-DOF horizontal plane model with 6 muscles. This simple model will allow the framework for the final simulator to be developed and tested. The model itself is very simple, allowing only horizontal shoulder and elbow flexion/extension, ensuring that all effort can go into development of the framework *per se*. Once that is in place, further development of the model can proceed without further changes in the inputs and output formats.

- DAS2: A 3-D model with scapula fixed to ground. This is significantly more complex than DAS1. It will include a 3-DOF glenohumeral joint and a 2-DOF elbow joint, but will simply the effort by using a fixed (rather than mobile) scapula and omitting the hand. The work will focus on changes that are necessary to reduce the simulation time of more comprehensive models to a real-time level. This will include simplifications in geometry (bundling of muscle elements, for example) as well as code optimization.
- DAS3: The final version with complete shoulder model, elbow and hand. This adds the complexity of closed kinematic chains formed by the scapula, clavicle and thorax and significantly increases the number of DOF. In addition, a one or two DOF for the hand will be added. The number of DOF at the shoulder may be reduced if the participant uses a mobile arm support to support the arm against gravity.

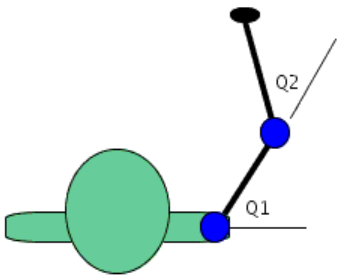

Figure 2 shows the 2 joint model, allowing horizontal shoulder and elbow flexion and extension.

Results: A 2-DOF horizontal plane model with 6 muscles was used to develop and test the framework. The mechanical configuration of this model is shown in Figure 2. It includes movements only in horizontal shoulder flexion and extension and elbow flexion and extension. On a 3GHz Pentium 4, the model runs approximately 50 times faster than real time. The model uses a PD (proportional-derivative) controller to control the joint angles, with simple rules for the muscle actions and fixed moment arms.

Figure 3 shows the results of the test simulation, in which the model starts from a certain position (arm straight and directed laterally) and moves to the target position defined in the input (shoulder flexed ~0.8 rad and elbow flexed ~ 1.6 rad). The model reaches the target position in approximately 60ms, while using just 1.2ms of processor time.

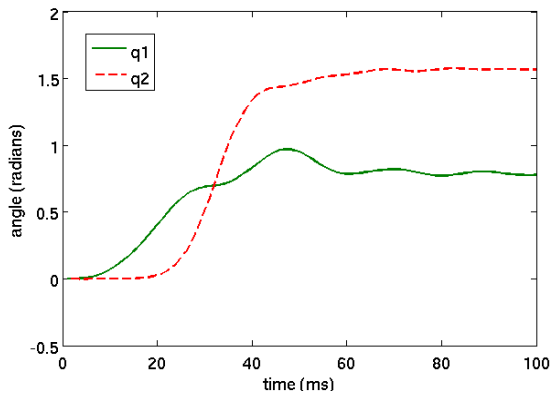

Figure 3 shows the results of a simulation using a joint-angle controller. q1 and q2 represent the shoulder and elbow joints respectively.

Discussion and interpretation:

The results of the 2-DOF test model represent a very promising start to the development of a real-time arm simulator. Although the model is very simple, it runs at ~50 times faster than real time on a modest PC. This implies significant room for increases in complexity whilst remaining below the real-time 'barrier'. The SD-Bio package developed by Dr. Ton van den Bogert (a collaborator on our NICHD-funded contract) was used in these simulations, and it provided a large speed gain over other modeling techniques that have been used previously.

Joint angles are used as inputs to the model in this version. It remains to be seen, however, whether this is the optimal control mode for the user. Other possibilities that can be handled by our modeling approach include joint velocities, end-point positions, and joint torques and muscle activations.

The Matlab MEX structure that we have adopted provides the easily ability for us to substitute one model for another. This will allow for easy upgrading as model development

takes place and will facilitate interaction with other parts of the project.

Future plans: The next two periods will involve the completion of DAS1 and finalization of the modeling framework, and the beginning of work on DAS2. The current model will take external inputs via Matlab, and display simulation results in a VR environment (see next section). Following that, work will begin on DAS2, a 5 DOF shoulder and elbow model with a fixed scapula. Work during this phase will focus on maintaining short simulation times while allowing for increased complexity of the model. Anatomical data for the model are available in an existing complete (but non-real-time) shoulder and elbow model previously developed in this lab.

4. Visualization of Simulated Arm Movements for Command Signal Evaluation

Rationale: Real-time visualization of the arm movements that would be produced by a given set of command signals (as simulated by the real-time model described in the previous section) will enable potential FES users to practice controlling their movements before they receive an implanted neuroprosthesis and will also enable us to evaluate a wide range of different command options and control strategies using both FES and non-FES subject pools.

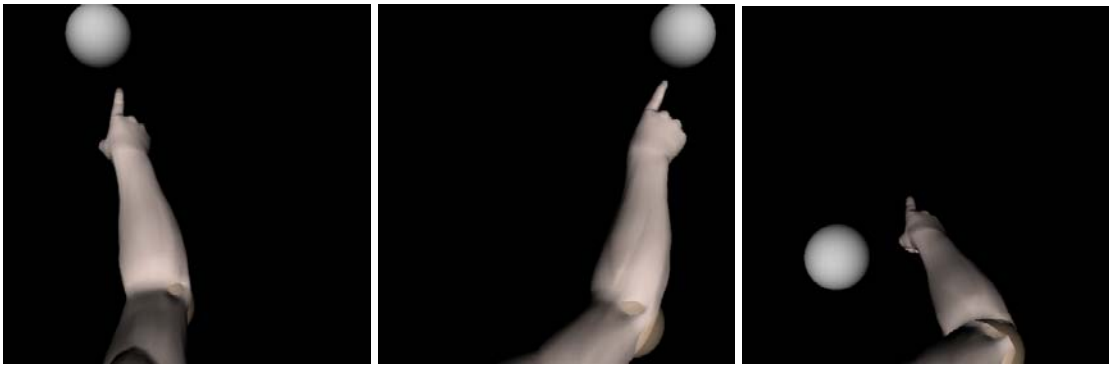

Figure 4: Screen shots of a virtual reality arm/hand that is displayed and manipulated in real time through Matlab's virtual reality toolbox. This initial prototype enables control of shoulder and elbow joint angles.

Results: Figure 4 shows screen shots of a virtual limb that can be displayed and manipulated in real time based on the command signals received. Currently, the elbow and shoulder joints are articulated but the wrist and fingers are not.

Discussion and interpretation: The work during this past quarter brought together the necessary software tools and demonstrated that a realistic rendition of the arm and hand can be displayed effectively to a potential FES user. Additional movements will be added incrementally as the real-time musculoskeletal model (see previous section) progresses.

Future plans: Over the next two reporting periods, we will provide the ability to display additional movements (in synchrony with the modeling work) and will improve the appearance of skin at the joints. We will also link the outputs of the real-time musculoskeletal model to the virtual arm to enable subjects to visualize how an actual FES-activated arm will respond and move based on the command signals given.

D. Concerns

There are no significant concerns at this time.